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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,929	12/02/2002	John J. Heine	1372.66.PRC	6456
21901	7590	06/15/2005	EXAMINER	
SMITH & HOPEN PA 15950 BAY VISTA DRIVE SUITE 220 CLEARWATER, FL 33760				LIN, JERRY
		ART UNIT		PAPER NUMBER
		1631		

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/065,929	HEINE ET AL.
Examiner	Art Unit	
Jerry Lin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 31 March 2005.

2a) This action is FINAL.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-12 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-12 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2 pages.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Species A, claim 1-12 in the reply filed on March 31, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Claim Objections***

Claim 1 is objected to because of the following informalities: "probability" in line 2 is misspelled. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the tolerance level" in line 6. There is insufficient antecedent basis for this limitation in the claim. The instant limitation was not mentioned previously in the instant claim. It is unclear if the tolerance level refers to the computer algorithm or the mammogram or some other limitation in the claim.

The term "higher" or "lower" in claim 1 is a relative term which renders the claim indefinite. The term "higher" or "lower" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

It is unclear what is meant by "responsive" in lines 7 and 9. For example, one interpretation of instant limitation is that higher probability values cause an increase of the tolerance level in the computer algorithm. Another interpretation is that the limitation increased tolerance levels occur while the computer algorithm has an unspecified response to the higher probability values. For purposes of the office action, the claim will be interpreted as the former.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 and 9, 10, 12 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Huo et al. (US 6,282,305).

Regarding claim 1 and claim 12, Huo et al. disclose a method which includes establishing a risk probability with a patient with factors such as age (column 5, lines 55-

63); applying a computer algorithm to find abnormalities in a patient's mammogram (column 9, lines 30-48); changing the tolerance levels for high risk and low risk patients (differentiating the patterns among high risk and low risk patients) (column 8, line 61-column 9, line 7).

Regarding claims 2 - 4, Huo et al. also discuss relative risk and absolute risk (column 3, lines 25-40) as well as include specific odds ratios in regard to breast cancer (column 3, line 66 - column 4, line 5).

Regarding claim 5, Huo et al. disclose determining parenchymal patterns (breast tissue density) (column 8, line 61-column 9, line 7; column 7, lines 18-37); integrating breast tissue density in the risk probability value (column 8, line 61-column 9, line 7; Figure 10).

Regarding claim 9, Huo et al. also disclose a data entry interface (Figure 13; column 29, lines 10-61); digitally acquiring the patient's mammogram (column 37, claim 45; column 29, lines 10-61); applying the algorithm to the mammogram (column 37, claim 45; column 29, lines 10-61).

Regarding claim 10, Huo et al. disclose storing risk factors on electronic storage medium with digitally acquire mammogram (column 37, claim 45 – column 38, claim 48; column 29, lines 10-61).

Claims 1, 6 - 9, 10, and 11 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Wang (US 6,266,435).

Regarding claim 1, Wang discloses establishing a risk probability value from risk factors (such as the pattern of the mammogram) (column 4, lines 17-38); applying a computer algorithm adapted to find abnormalities (column 7, lines 10-37); increasing or decreasing the tolerance rate for false positives in relation to the probability valued (column 8, line 14 - column 9, line 7).

Regarding claims 6 and 7, Wang discloses flagging (marking or annotating) positive or negative results of mammograms (column 8, lines 47-65).

Regarding claim 8, based on the results of the method, the physician recommends a course of action, which would include more invasive procedures for high probability of breast cancer or less invasive procedures for low probability of breast cancer (column 2, lines 51-55).

Regarding claim 9, Wang also discloses a system wherein risk factors are inputted (i.e., the probability threshold for the patient) (column 8, lines 30-35); digitally acquiring the mammogram (column 7, lines 10-27); applying the algorithm to the mammogram to find abnormalities (column 5, lines 40-50).

Regarding claim 10, Wang discloses storing the risk factors and digital mammogram on electronic storage medium (Figure 1).

Regarding claim 11, Wang discloses presenting the results with computer aided enhancement (column 7, lines 37-56).

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 6:30-5:00, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Ardin H. Marschel 6/13/05*  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**

JL